

# MEDICARE AND THE JOINT COMMISSION ON ACCREDITATION OF HEALTHCARE ORGANIZATIONS: A HEALTHY RELATIONSHIP?

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## I

### INTRODUCTION

Country-wide, more than 5000 hospitals are permitted to provide Medicare-financed services solely because they are accredited by the Joint Commission on Accreditation of Healthcare Organizations (the "JCAHO" or the "Joint Commission"). With JCAHO accreditation, a health care institution is deemed to meet the Medicare conditions of participation. This "deemed status" program is the oldest and most substantial regulatory use of health care accreditation in the United States. This article will critically consider the economic and political forces driving the program and will examine why the federal government has relied on private accreditation in health care and whether this reliance is in the public interest.

This article will first describe the JCAHO and its accreditation programs, then review the history of the Medicare-JCAHO relationship, next examine why the federal Medicare program has relied on accreditation as an indicator of the quality of participating hospitals, and finally consider, in theory and practice, the extent to which accreditation status serves as an adequate substitute for direct public regulation of the quality of health care institutions.

## II

### THE JOINT COMMISSION ON ACCREDITATION OF HEALTHCARE ORGANIZATIONS

The JCAHO is a private, nonprofit corporation that currently accredits more than 9000 health care institutions, including about 5400 hospitals.<sup>1</sup> Its twenty-six member board includes twenty-one commissioners appointed by the American Medical Association (seven commissioners), the American Hospital Association (seven), the American College of Physicians (three), the American

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1. Linda Oberman, *Spot Inspections Planned to Add Accreditation Credibility*, 39 AM. MED. NEWS, Feb. 22, 1993, at 6.

College of Surgeons (three), and the American Dental Association (one).<sup>2</sup> The remaining commissioners consist of one nurse and four (six starting in 1994) members of the general public. The JCAHO has an annual budget of \$80 million and 450 employees at its headquarters, as well as 150 full-time and 350 part-time surveyors and consultants.

The JCAHO grew out of the Hospital Standardization Program (the "HSP") of the American College of Surgeons (the "ACS").<sup>3</sup> The HSP began in 1919 as an attempt to standardize hospital facilities in the face of the appalling conditions then common in institutional health care.<sup>4</sup> The JCAHO itself was established in 1951 as a joint effort of the major organizations representing hospitals and physicians when the burden of the HSP became too great for the ACS to bear alone.<sup>5</sup> Although the hospital accreditation program is its oldest and best known program, the JCAHO enjoys similar authority over ambulatory care,<sup>6</sup> long-term care,<sup>7</sup> and psychiatric facilities,<sup>8</sup> as well as home care programs.<sup>9</sup> It has recently established an accreditation program for health care networks.<sup>10</sup> In addition, the JCAHO produces a variety of publications and offers technical assistance and consulting services to health care facilities.<sup>11</sup>

Hospitals accredited by the JCAHO are surveyed at least once every three years. At minimum, a survey team includes a hospital administrator, a

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2. Joint Commission Bylaws, Article VI, Section 1. A slightly dated description of the Joint Commission is found in JOINT COMMISSION ON ACCREDITATION OF HEALTHCARE ORGANIZATIONS, COMMITTED TO QUALITY: AN INTRODUCTION TO THE JOINT COMMISSION ON ACCREDITATION OF HEALTHCARE ORGANIZATIONS (1990) [hereinafter JOINT COMMISSION].

3. Histories of the HSP and of the Joint Commission are found in Timothy Stoltzfus Jost, *The Joint Commission on Accreditation of Hospitals: Public Regulation of Health Care and the Public Interest*, 24 B.C. L. REV. 835, 845-59 (1983); James S. Roberts et al., *A History of the Joint Commission on Accreditation of Hospitals*, 258 JAMA 936 (1987).

4. Jost, *supra* note 3, at 848; Roberts, *supra* note 3, at 936.

5. Jost, *supra* note 3, at 850-51; Roberts, *supra* note 3, at 938.

6. This category includes ambulatory care clinics, ambulatory surgical centers, college or university health programs, community health centers, group practices, armed services ambulatory programs, cardiac catheterization centers, Native American health service centers, primary care centers, and urgent/emergency care centers. JOINT COMMISSION, *supra* note 2, at 15.

7. This category includes both hospital-based and free-standing facilities. *Id.* at 16.

8. This category includes alcohol and substance abuse programs, community mental health centers, forensic psychiatry services, programs for persons with mental retardation and/or other developmental disabilities, and general psychiatric/mental health programs. *Id.*

9. This category includes private duty agencies providing care at home, rehabilitation organizations providing speech/language pathology, occupational, and/or physical therapy services in the home, intravenous therapy companies, organizations providing respiratory services in the home, home medical equipment companies providing equipment and patient/client instruction in the home, and pediatric home care agencies. *Id.*

10. JOINT COMMISSION ON ACCREDITATION OF HEALTHCARE ORGANIZATIONS, 1994 JOINT COMMISSION STANDARDS FOR HEALTH CARE NETWORKS (1994) [hereinafter JOINT COMMISSION STANDARDS].

11. See JOINT COMMISSION, *supra* note 2, at 49-56. Although the Joint Commission maintains that it has established procedures to avoid conflicts, concerns have been raised about the potential conflict of interest of the Joint Commission both accrediting health care facilities and marketing consulting services to advise facilities how to obtain accreditation. Brian McCormick, *GAO Faults Public, Private Hospital Accreditation*, 34 AM. MED. NEWS, June 10, 1991, at 8.

physician, and a nurse.<sup>12</sup> The survey generally lasts three days. At the conclusion of the survey, the surveyors score each of hundreds of applicable standards on a scale from one to five. These scores are then aggregated using complex algorithms to reach an accreditation decision.<sup>13</sup> While approximately one-quarter of surveyed hospitals receive full accreditation, most receive accreditation with contingencies that must be resolved through further reports or inspections.<sup>14</sup> Less than one percent of the hospitals surveyed are denied accreditation.<sup>15</sup>

The JCAHO updates its accreditation standards regularly, based on input from its staff, advisory committees, and outside experts.<sup>16</sup> Traditionally, JCAHO accreditation standards focused on the structural inputs (policies, equipment, staffing) found within hospitals.<sup>17</sup> Over the past four years, the Commission has aggressively pursued its Agenda for Change,<sup>18</sup> which shifts its focus toward an emphasis on processes and outcomes.<sup>19</sup> Under the Agenda for Change, the JCAHO is revising its accreditation manuals to streamline its standards, redirect its standards from their current focus on departmental organization to a focus on institutional functions or processes, stress the interdisciplinary task of assessing and improving quality, increase the flexibility afforded providers in complying with the standards, and emphasize performance. It is also developing outcome indicators that will allow hospitals to monitor trends and patterns of care with the aim of improving patient care.<sup>20</sup> Finally, it is concurrently revising its survey process to make it more timely, consistent, and useful to accredited institutions.

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12. JOINT COMMISSION, *supra* note 2, at 24-26.

13. See JOINT COMMISSION ON ACCREDITATION OF HEALTHCARE ORGANIZATIONS, MAKING ACCREDITATION DECISIONS FOR HOSPITALS (1993).

14. See *Full Survey Decision Outcomes*, JOINT COMMISSION PERSPECTIVES, July-Aug. 1991, at 16.

15. *Id.*

16. See *infra* text accompanying notes 170-71; see also Jost, *supra* note 3, at 886-92. The Joint Commission claims that 42 states rely in whole or in part on its accreditation for licensure of hospitals. JOINT COMMISSION ON ACCREDITATION OF HEALTHCARE ORGANIZATIONS, STATE STATUS REPORT (1992). In response to a recent survey conducted by the advocacy group Public Citizen, 26 states identified themselves as relying solely on JCAHO accreditation for licensure of hospitals, 16 stated that they did not rely on accreditation, and the remaining states considered JCAHO results or otherwise utilized JCAHO surveys or survey reports in their licensure process. JOAN STIEBER & SIDNEY M. WOLFE, WHO'S WATCHING OUR HOSPITALS? 8-9 (1994).

17. Michael G. H. McGeary, *Medicare Conditions of Participation and Accreditation for Hospitals*, in 2 MEDICARE: A STRATEGY FOR QUALITY ASSURANCE 292, 311-17 (Kathleen N. Lohr ed., 1990).

18. See JOINT COMMISSION, *supra* note 2, at 41-43.

19. Mary T. Koska, *New JCAHO Standards Emphasize Continuous Quality Improvement*, HOSPITALS, Aug. 5, 1991, at 41; Joyce A. Lanning & Stephen J. O'Connor, *Health Care Quality Quagmire: Some Signposts*, 35 HOSP. & HEALTH SERVICES ADMIN. 39 (1990); Richard E. Thompson, *From Quality Assurance to Continuous Quality Improvement*, PHYSICIAN EXECUTIVE, Sept.-Oct. 1991, at 3.

20. See Mary T. Koska, *JCAHO: Pilot Hospitals' Input Updates Agenda for Change*, HOSPITALS, Jan. 5, 1990, at 50 (describing the Agenda for Change); Koska, *supra* note 19, at 41 (same); Dennis S. O'Leary, *Accreditation in the Quality Improvement Mold—A Vision for Tomorrow*, QRB, Mar. 1991, at 72 (same); see also David Burda, *JCAHO Hits a Wall With Plan on Indicators*, MOD. HEALTHCARE, Mar. 14, 1994, at 30 (describing problems encountered in this effort).

## III

## THE JOINT COMMISSION AND MEDICARE RELATIONSHIP: HISTORY AND CURRENT STATUS

The federal Medicare program was created in 1965. Since its inception, the Medicare program has accepted, or "deemed," Joint Commission accreditation as equivalent to compliance with Medicare certification standards. That is, the federal government accepts accredited hospitals as Medicare providers without additional direct review.<sup>21</sup> The original 1965 Medicare statute acknowledged JCAHO authority not only by granting deemed status to JCAHO-accredited hospitals,<sup>22</sup> but also by prohibiting the federal government from imposing any additional requirements on such hospitals.<sup>23</sup> Furthermore, the statute made no provision for federal auditing of the Joint Commission's accreditation process. Indeed, the Department of Health, Education, and Welfare ("HEW")—the agency charged with administering Medicare—did not even have access to JCAHO accreditation reports to determine the basis (or lack thereof) for accreditation decisions.<sup>24</sup>

In the late 1970s, several consumer groups expressed dissatisfaction with using JCAHO accreditation as conclusive evidence of acceptable quality in hospitals.<sup>25</sup> This dissatisfaction led to the filing of a lawsuit challenging deemed status.<sup>26</sup> Amendments to the Social Security Act in 1972 responded to these concerns. Statutory changes permitted HEW to require accredited hospitals to comply with Medicare certification standards more stringent than those of the JCAHO,<sup>27</sup> required random and complaint-based inspections by state agencies to validate JCAHO judgments,<sup>28</sup> permitted decertification of

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21. A separate certification program was created to grant Medicare participation status based on inspections by state survey agencies to hospitals that were not Joint Commission accredited. 42 U.S.C. § 1395x(e) (1988 & Supp. III 1991); 42 C.F.R. §§ 482.1-482.66 (1993).

22. Social Security Amendments of 1965, Pub. L. No. 89-97, sec. 102(a), § 1865, 79 Stat. 286, 326-27 (codified as amended at 42 U.S.C. § 1395bb (1988 & Supp. III 1991)). Accredited hospitals also had to have a utilization review plan in place to be certified for Medicare participation, though the statute provided that if the Joint Commission required utilization review, accredited hospitals would not be required to meet this requirement independent of accreditation.

23. *Id.* § 1861(e)(8), 79 Stat. at 315; see William Worthington & Laurens H. Silver, *Regulation of Quality of Care in Hospitals: The Need for Change*, 35 LAW & CONTEMP. PROBS. 305, 313 (Spring 1970) (discussing this provision). This provision was subject to the exception that if states imposed requirements higher than JCAHO requirements for their Medicaid programs or obtained federal permission to impose higher requirements for Medicare hospitals, the federal government would require hospitals to meet these requirements. Social Security Amendments of 1965, Pub. L. No. 89-97, sec. 102(a), §§ 1863, 1865, 79 Stat. 286, 325-27; Worthington & Silver, *supra*, at 322, 323.

24. See Social Security Amendments of 1965, Pub. L. No. 89-97, sec. 102(a), §§ 1861(e)(8), 1865, 79 Stat. 286, 315, 326-27.

25. Jost, *supra* note 3, at 855-56.

26. *Self-Help for the Elderly v. Richardson*, No. 2016-71 (D.D.C. 1972). This case was dismissed after the 1972 amendments mooted the issues it raised.

27. Social Security Amendments of 1972, Pub. L. No. 92-603, § 244(b)(1), 86 Stat. 1329, 1423 (codified at 42 U.S.C. § 1395bb(a)(4) (1988)).

28. 42 U.S.C. § 1395aa(c) (1988).

accredited hospitals that failed to comply with JCAHO requirements,<sup>29</sup> and compelled accredited hospitals to release Joint Commission survey reports to HEW for validation survey purposes.<sup>30</sup> The 1972 amendments established the basic framework for the ongoing relationship between Medicare and the Joint Commission.

In the intervening two decades, there have been adjustments of that relationship with respect to information disclosure and validation procedures. In 1975, in response to a consumer organization's Freedom of Information Act request, HEW released copies of letters that the Joint Commission had sent to hospitals identifying deficiencies and that HEW had received from those hospitals under the 1972 amendments.<sup>31</sup> The Joint Commission sued to maintain the confidentiality of its accreditation documents.<sup>32</sup> The parties settled the suit with an agreement that HEW would not release to the public Joint Commission accreditation letters or accompanying recommendations or comments.<sup>33</sup>

In 1989, Congress amended the Medicare law to grant the Department of Health and Human Services ("HHS") (which succeeded HEW in administering Medicare) more extensive access to accreditation documents. That legislation required all deemed status hospitals to authorize the Joint Commission to release, upon request, to HHS or to a state survey agency a copy of the most recent Joint Commission accreditation survey, whether or not the facility was undergoing a validation survey.<sup>34</sup> These amendments respected the 1975 compromise, however, authorizing HHS to redisclose accreditation information only to the extent it related to an enforcement action taken by the Secretary of HHS.<sup>35</sup>

In 1990 and 1991, the General Accounting Office ("GAO") released several reports expressing concern about the federal government's validation process for deemed status hospitals, and congressional hearings were held to review these concerns.<sup>36</sup> In response, HHS attempted to tighten up the validation process, in particular, committing itself to creating an annual "crosswalk" to determine

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29. *Id.* § 1395bb(b).

30. *Id.* § 1395bb(a).

31. Jost, *supra* note 3, at 856.

32. Joint Comm'n on Accreditation of Hosp. v. Weinberger, No. 75C175 (N.D.Ill. Oct 8, 1975) (dismissed by stipulation).

33. *Id.*

34. Omnibus Budget Reconciliation Act of 1989, Pub. L. No. 101-239, § 6019(a), 103 Stat. 2106, 2165-66 (codified at 42 U.S.C. § 1395bb(a)(2)(A) (1988 & Supp. III 1991)).

35. 42 U.S.C. § 1395bb(a) (1988).

36. GAO, HEALTH CARE: HCFA NEEDS BETTER ASSURANCE THAT HOSPITALS MEET MEDICARE CONDITIONS OF PARTICIPATION, GAO DOC. T-HRD-90-44 (June 21, 1990); GAO, HEALTH CARE CRITERIA USED TO EVALUATE HOSPITAL ACCREDITATION PROCESS NEED REEVALUATION, GAO DOC. HRD-90-89 (June 11, 1990) [hereinafter GAO, CRITERIA]; GAO, HEALTH CARE: HOSPITALS WITH QUALITY-OF-CARE PROBLEMS NEED CLOSER MONITORING, GAO DOC. HRD-91-40 (May 9, 1991) [hereinafter GAO, MONITORING]; GAO, HEALTH CARE: ACTIONS TO TERMINATE PROBLEM HOSPITALS FROM MEDICARE ARE INADEQUATE, GAO DOC. HRD-91-54 (Sept. 5, 1991) [hereinafter GAO, INADEQUATE].

the congruence between Joint Commission accreditation standards and the Medicare conditions of participation on which deemed status depends.<sup>37</sup> This crosswalk, which HHS now attempts to create annually, is intended to assure that compliance with accreditation standards in fact equates with compliance with the Medicare conditions of participation.

Though the Joint Commission's role in determining Medicare participation status for hospitals is its most important federal regulatory function, it is not the only instance in which the federal government has relied on the Joint Commission for regulation. Until 1984, psychiatric hospitals had to be accredited by the Joint Commission to participate in the Medicare and Medicaid programs in most instances.<sup>38</sup> In particular, inpatient psychiatric hospitals for persons under the age of twenty-one could provide Medicaid-financed care only if they were Joint-Commission accredited.<sup>39</sup> *Cospito v. Heckler*<sup>40</sup> upheld the constitutionality of this legislation against an improper delegation challenge, but only after the court imposed a very strained interpretation on the statute. Congress amended the law in 1984 to eliminate the accreditation requirement.<sup>41</sup>

The federal government has also relied upon private accreditation of medical laboratories. The Clinical Laboratories Improvement Act of 1967 ("CLIA") exempted laboratories in Joint Commission-accredited hospitals or laboratories accredited by organizations approved by the Secretary of HEW from the Act's licensing requirements.<sup>42</sup> The 1988 revision of CLIA removed this provision, instead permitting deemed status for accredited laboratories only upon a determination by HHS that the accreditation agency meets HHS requirements for frequency of inspections, stringency of standards, and communication with HHS.<sup>43</sup> The Joint Commission has applied for deemed status recognition for laboratories it accredits, but HHS has taken no final action on this application.

In May of 1981, the Reagan Department of HHS proposed deemed status certification of Joint Commission-accredited nursing homes.<sup>44</sup> This proposal met strong opposition from consumer groups, who feared that it would lead to a weakening of state and federal efforts to enforce quality of care standards in

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37. McCormick, *supra* note 11, at 8.

38. 42 U.S.C. 1395x(f)(5) (repealed by Pub. L. No. 99-369, § 2340 (1984)).

39. *Id.* § 1396d(a)(16); 42 C.F.R. § 440.140 (1983).

40. 742 F.2d 72 (3d Cir. 1984); *see also* Leone v. Mathews, No. 76-1059 (D.N.J. Aug. 2, 1977) (finding no unconstitutional delegation to JCAHO of responsibility to certify psychiatric facilities for Medicare and Medicaid where federal government could certify facilities as distinct parts of hospitals).

41. Deficit Reduction Act of 1984, Pub. L. No. 98-369, § 2340(a), 98 Stat. 494, 1093 (codified at 42 U.S.C. § 1395x(f) (1988)); *see also* Michael J. Astrue, *Health Care Reform and the Constitutional Limits on Private Accreditation as an Alternative to Direct Government Regulation*, 57 LAW & CONTEMP. PROBS. 75, 79-80 (Autumn 1994).

42. Pub. L. No. 90-174, 81 Stat. 536 (codified as amended at 42 U.S.C. § 263a (1988)).

43. 42 U.S.C. § 263a(e) (1988); 42 C.F.R. §§ 493.501-.511 (1992).

44. 47 Fed. Reg. 23,404 (1982) (proposed May 27, 1982).

nursing homes. After two congressionally imposed moratoria and congressional hearings, HHS abandoned its proposal.<sup>45</sup>

HHS is permitted to grant Medicare deemed participation status to a wide variety of accredited institutions<sup>46</sup> if the Secretary of HHS finds that accreditation by a national body provides reasonable assurances that Medicare certification conditions are met.<sup>47</sup> Regulations to implement this statute were adopted in November of 1993 and are discussed elsewhere in this symposium.<sup>48</sup> Under a proposed version of these regulations, on June 30, 1993, the Health Care Financing Administration ("HCFA")—the body of HHS that administers Medicare—permitted Joint Commission-accredited home health organizations to receive deemed status.<sup>49</sup>

Though this article is concerned with the relationship between the Joint Commission and the federal Medicare program, it should be noted that the states also rely extensively on Joint Commission accreditation in regulating health care providers. About two-thirds of the states base hospital licensure, in whole or in part, on Joint Commission accreditation.<sup>50</sup> States also rely on Joint Commission accreditation for purposes as varied as defining approved clinical training for the licensing of professionals<sup>51</sup> and specifying institutions whose services must be covered under insurance mandates.<sup>52</sup> Finally, state courts rely on Joint Commission accreditation for specifying standards of care in malpractice cases,<sup>53</sup> and as evidence of the adequacy of treatment facilities in cases

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45. See INSTITUTE OF MEDICINE, IMPROVING THE QUALITY OF CARE IN NURSING HOMES 1-2 (1986); Jost, *supra* note 3, at 844; see also Iris C. Freeman, *Blast or Boost? How the Joint Commission Fared in the Institute of Medicine's Nursing Home Study*, QRB, Dec. 1986, at 415.

46. See 42 U.S.C. § 1395bb (1988 & Supp. III 1991). The institutions include psychiatric hospitals, skilled nursing facilities, home health agencies, ambulatory surgical centers, rural health clinics, comprehensive outpatient rehabilitation facilities, hospices, laboratories, and clinics, rehabilitation agencies, or public health agencies providing outpatient physical therapy, occupational therapy, or speech pathology services. *Id.*

47. *Id.*

48. 58 Fed. Reg. 61,816 (1993) (to be codified at 42 C.F.R. pts. 401, 488, 489); see Astrue, *supra* note 41; Eleanor D. Kinney, *Private Accreditation as a Substitute for Direct Government Regulation in Public Health Insurance Programs: When is it Appropriate?*, 57 LAW & CONTEMP. PROBS. 47 (Autumn 1994).

49. 58 Fed. Reg. 35,007 (1993); see also GAO, HOME HEALTH CARE: HCFA PROPERLY EVALUATED JCAHO'S ABILITY TO SURVEY HOME HEALTH AGENCIES (Oct. 26, 1992) (reviewing HCFA's review of this application).

50. See, e.g., ALASKA STAT. § 18.20.080(a) (1993) (hospitals); GA. CODE ANN. § 31-7-3(b) (1991) (health facilities); IOWA CODE ANN. § 135J.2 (West Supp. 1994) (hospices); MD. CODE ANN., HEALTH-GEN. § 8-403(d)(1) (1994) (alcohol and drug abuse treatment programs); MD. CODE ANN., MENTAL HYGIENE § 504(d)(1) (mental health facilities); MO. REV. STAT. § 630.705.3(3), (6) (1988) (mental hospitals); N.C. GEN. STAT. § 131E-138(g)(i) (1991) (home health agencies); OHIO REV. CODE ANN. § 3727.02(A) (Baldwin 1992) (hospitals).

51. See, e.g., CAL. BUS. & PROF. CODE § 2089.5(e)(3) (West 1990) (physicians); IND. CODE ANN. §§ 20-12 to 30.5-7 (Burns 1991) (physicians).

52. See, e.g., HAW. REV. STAT. § 393-7(c)(6)(C) (Michie 1993) (detoxification); KY. REV. STAT. ANN. § 304.18-140(2) (Baldwin 1992) (detoxification); NEV. REV. STAT. ANN. § 608.156(4)(b) (Michie 1992) (drug and alcohol benefits).

53. See, e.g., *Jackson v. Power*, 743 P.2d 1376, 1382-83 (Alaska 1987); *Shilkret v. Annapolis Emergency Hosp. Ass'n*, 349 A.2d 245, 254 (Md. 1975); *Pedroza v. Bryant*, 677 P.2d 166, 171 (Wash. 1984).

alleging unconstitutional conditions of confinement in prisons or mental institutions.<sup>54</sup>

#### IV

##### WHY DOES THE MEDICARE PROGRAM DEPEND ON JOINT COMMISSION ACCREDITATION FOR ASSURING THE QUALITY OF HEALTH CARE PROVIDERS?

The quality of medical care provided to Medicare beneficiaries should be a major concern of Congress and of HHS. It is widely believed that health care consumers lack the ability to evaluate important aspects of the quality of medical care.<sup>55</sup> Older and sicker patients, who consume the vast majority of Medicare-financed care, may be even less capable than younger and healthier patients of evaluating the quality of institutional care in making purchasing decisions. Even informed patients may have little or no choice among health care institutions if they live in rural or other medically underserved areas, or are hospitalized in an emergency. Finally, regardless of its responsibilities to its beneficiaries, Medicare arguably has an independent obligation to taxpayers to assure that the \$156 billion it spends annually funds care of adequate quality.

Given the importance of assuring the quality of Medicare-financed institutional health care, it is remarkable that throughout its existence Medicare has depended on a private organization to fulfill this function. Perhaps of greater concern is the fact that the federal government has, for a time almost totally, relied on an organization sponsored by medical care providers to determine institutional quality. The Medicare mechanism for quality control, therefore, depends upon what appears to be self-regulation of the health care industry.

A complete explanation of Medicare's reliance on Joint Commission accreditation status must address three questions. First, why did Congress, at the outset of Medicare, adopt Joint Commission accreditation as the primary criterion for determining the quality of hospitals? Second, why has Congress continued to rely on the Joint Commission for determining Medicare participation status instead of using alternative regulatory entities such as state survey agencies or Medicare peer review organizations? Third, why has the federal government (more specifically HCFA) not undertaken the task of determining

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54. See, e.g., *Woe v. Cuomo*, 729 F.2d 96, 106 (2d Cir. 1984); *Concerned Citizens for Creedmoor Inc. v. Cuomo*, 570 F. Supp. 575, 576-77 (E.D.N.Y. 1983).

55. See 1 INSTITUTE OF MEDICINE, *MEDICARE: A STRATEGY FOR QUALITY ASSURANCE* 35 (Kathleen N. Lohr ed., 1990); 1 AVEDIS DONABEDIAN, *EXPLORATIONS IN QUALITY ASSESSMENT AND MONITORING THE DEFINITION OF QUALITY AND APPROACHES TO ITS ASSESSMENT* 5 (1980); Timothy Stoltzfus Jost, *The Necessary and Proper Role of Regulation to Assure the Quality of Health Care*, 25 HOUS. L. REV. 525, 558-68 (1988); see also Timothy Stoltzfus Jost, *Health System Reform: Forward or Backward in Quality Oversight?*, 271 JAMA 1508 (1994) (criticizing recent proposals to correct information problems through quality report cards).



Medicare participation status for health care institutions? These questions will be addressed seriatim.

#### A. The Origins of Deemed Status

The creation of the Medicare program was an important milestone in the long and hard-fought battle for national health insurance.<sup>56</sup> Organized medicine had vigorously opposed the adoption of such a program.<sup>57</sup> President Lyndon Johnson, with considerable assistance at the last minute from Wilbur Mills, the powerful chair of the House Ways and Means Committee, was able to force the program through a Congress heavily controlled by Democrats.<sup>58</sup> Having won the legislative battle, however, the architects of Medicare faced almost certain failure in implementing the program unless they could rapidly bring health care providers, including physicians, to embrace it.<sup>59</sup> The program drafters' primary, indeed nearly all-absorbing, goal was to increase the elderly's access to health care services.<sup>60</sup> Goals of controlling program costs came in second, with assuring quality health care a distant third.<sup>61</sup> With respect to the access criterion, the success or failure of Medicare turned on whether enough health care professionals and institutions would participate in the program to make it viable.

To increase the likelihood of professional and institutional participation, Medicare was designed to mimic conventional health insurance programs, to which health care providers were, by the mid-1960s, quite accustomed.<sup>62</sup> It reimbursed providers for their costs in supplying services to Medicare beneficiaries, much like existing Blue Cross and Blue Shield plans.<sup>63</sup> Physician reimbursement was charge-based, and physicians had the option of billing their patients directly (with the patients then being indemnified by Medicare for a portion of the charge) or billing Medicare directly on an assignment basis.<sup>64</sup> Medicare was even administered through private insurance companies, which spared professionals and providers the indignity of dealing with the federal government.<sup>65</sup>

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56. See PETER A. CORNING, *THE EVOLUTION OF MEDICARE FROM IDEA TO LAW* (1969); RICHARD HARRIS, *A SACRED TRUST* (1966); THEODORE R. MARMOR, *THE POLITICS OF MEDICARE* (1973).

57. See generally HARRIS, *supra* note 56.

58. See *id.* at 162-92; MARMOR, *supra* note 56, at 59-81.

59. JUDITH M. FEDER, *MEDICARE: THE POLITICS OF FEDERAL HOSPITAL INSURANCE* 11 (1977); MARMOR, *supra* note 56, at 83-84; JAMES A. MARONE, *THE DEMOCRATIC WISH: POPULAR PARTICIPATION AND THE LIMITS OF AMERICAN GOVERNMENT* 263-64 (1990); David Blumenthal, *Medicare: The Beginnings*, in *RENEWING THE PROMISE* 3, 17 (David Blumenthal et al. eds., 1988).

60. MARMOR, *supra* note 56, at 79.

61. FRANK J. THOMPSON, *HEALTH POLICY AND THE BUREAUCRACY* 176-77 (1981).

62. See Blumenthal, *supra* note 59, at 13, 14; MARMOR, *supra* note 56, at 78, 80.

63. MARONE, *supra* note 59, at 263; Thompson, *supra* note 19 at 157; see ERWIN WITKIN, *THE IMPACT OF MEDICARE* 64 (1971).

64. MARMOR, *supra* note 56, at 80; Thompson, *supra* note 19, at 158.

65. ROBERT J. MYERS, *MEDICARE* 175 (1970). The use of carriers and intermediaries also spared the federal government from having to develop its own payment infrastructure and allowed it to build

Central to this access-expansion strategy was the noninterference principle, still enshrined in Section One of Title XVIII of the Medicare statute:

Nothing in this title shall be construed to authorize any Federal officer or employee to exercise any supervision or control over the practice of medicine or the manner in which medical services are provided . . . or to exercise any supervision or control over the administration or operation of any . . . institution, agency, or person [providing health services].<sup>66</sup>

Under this principle, federal regulation of providers was to be minimal. Utilization of hospital services was to be reviewed, but the statute delegated responsibility for carrying out this function to the hospitals themselves.<sup>67</sup> Nonaccredited hospitals and "extended care facilities" required certification to participate in Medicare,<sup>68</sup> but the federal government relied on state agencies for this certification, eschewing the creation of an independent federal bureaucracy to oversee health care.<sup>69</sup> The primary relationship in the Medicare program was between the program and its beneficiaries, who enrolled in the program, paid their premiums, and either assigned their right to payment for specific medical services to their physicians or sought indemnification for bills they paid themselves.<sup>70</sup>

It was in this context that deemed Medicare certification status for Joint Commission-accredited hospitals was conceived. A program had to be devised that would assure that the vast majority of the nation's hospitals would be willing and able to participate almost immediately, making hospital services readily available to the elderly regardless of where they lived.<sup>71</sup> The short period of time over which the program was to be implemented—less than a year—and the nonintervention policy just discussed militated against the creation of a massive federal bureaucracy to regulate hospitals.<sup>72</sup> Nevertheless, some mechanism was necessary to determine whether participating institutional providers were in fact what they purported to be and to assure minimum quality.

Reliance on Joint Commission accreditation for determining Medicare participation status seemed an ideal solution. Most large hospitals in the nation were already Joint Commission-accredited, and Joint Commission accreditation

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on the experience of existing insurance organizations.

66. 42 U.S.C. § 1395 (1988).

67. WITKIN, *supra* note 63, at 117-26; Thompson, *supra* note 19, at 157-58.

68. See John W. Cashman & Beverlee A. Meyers, *Medicare: Standards of Service in a New Program—Licensure, Certification, Accreditation*, 57 AM. J. PUB. HEALTH 1107 (1967); Worthington & Silver, *supra* note 23, at 310-17.

69. MYERS, *supra* note 65, at 177-78.

70. This program stance was, it should be noted, readily accepted by the Social Security Administration ("the SSA"), which at the outset administered the Medicare program. The SSA has traditionally been a bill-paying agency, and had little interest in becoming a regulatory agency. See Judith M. Feder, *The Social Security Administration and Medicare: A Strategy of Implementation*, in TOWARD A NATIONAL HEALTH POLICY 19 (Kenneth M. Friedman & Stuart H. Rakoff eds., 1977).

71. FEDER, *supra* note 59, at 11.

72. *Id.* at 11; McGeary, *supra* note 17, at 302, 303.

was generally recognized as a symbol of acceptable hospital quality.<sup>73</sup> Because health care professionals and providers controlled the Joint Commission, providers viewed oversight by the Joint Commission as more acceptable than direct federal regulation.<sup>74</sup> Therefore, the original Medicare statute, discussed above, not only accepted Joint Commission accreditation as "deemed status" for program certification (thus obviating the creation of a federal program), but also prohibited the federal government from imposing additional requirements on hospitals beyond those imposed by the Joint Commission<sup>75</sup> (thus satisfying the noninterference principle).

#### B. Why Has Medicare Continued to Rely on Joint Commission Accreditation In Lieu of Alternative Regulatory Approaches?

While the peculiar circumstances that attended the origins of Medicare explain how deemed status came to be, they do not explain its durability. The Medicare implementation strategy discussed above in fact worked. A boycott threatened by physicians fizzled, and by July 1, 1966, when Medicare became operational, an ample supply of providers and professionals was available to accept Medicare beneficiaries as patients.<sup>76</sup> The faults of this hands-off strategy quickly became apparent, however.<sup>77</sup> By 1970, when *Law and Contemporary Problems* published a two-volume symposium on health policy,<sup>78</sup> problems of overutilization, poor quality care, and program and patient fraud and abuse were fully evident.

Over the last two decades, Congress and HHS have continued to expand the federal regulatory response to these problems. As this has occurred, the nature of the Medicare program has changed gradually yet dramatically. Though the noninterference principle enshrined in section 1801<sup>79</sup> has never been repealed, it exists today only as an anachronism. Medicare has ceased to function as an indemnity insurer that pays for services purchased by its beneficiaries. Rather it has itself become a purchaser of services, immersed in regulating the professionals and providers whom it pays to deliver services to its beneficiaries. For example, at the outset of the program, many physicians billed Medicare beneficiaries directly for services at any rate they chose, with the beneficiary in turn seeking indemnification from Medicare, often at a lower rate. Accepting "assignment" of a claim from the patient as payment in full and billing Medicare

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73. FEDER, *supra* note 59, at 7-9; Jost, *supra* note 3, at 854.

74. Jost, *supra* note 3, at 854; Telephone Interview with Wilbur Cohen, former Assistant Secretary of HEW for legislation, 1961-1965, former Undersecretary of HEW, 1965-1967, former Secretary of HEW, 1968-1969 (Aug. 30, 1982).

75. See *supra* notes 21-22 and accompanying text.

76. HARRIS, *supra* note 56, at 215-18; MARONE, *supra* note 59, at 264; Cashman & Meyers, *supra* note 68, at 1114; Thompson, *supra* note 19, at 161-62.

77. MARMOR, *supra* note 56, at 85-93, 122-23.

78. See Symposium, *Health Care*, 35 LAW & CONTEMP. PROBS. (Spring & Autumn 1970), and, in particular, Irwin Wolkstein, *Medicare 1971: Changing Attitudes and Changing Legislation*, 35 LAW & CONTEMP. PROBS. 697 (Autumn 1970).

79. 42 U.S.C. § 1395 (1988).

directly was an alternative available for physicians who wanted to make sure that they received payment, but Medicare had not pressed this as the favored alternative. Though physicians can still bill patients directly today, Congress has steadily moved to discourage this behavior. In 1983, Congress established various incentives to encourage physicians to become "participating providers" who accept assignment of all claims. Then in 1986, it imposed Maximum Allowable Actual Charge limits on nonparticipating physicians. Finally, the physician payment reforms of 1989 limited to an even greater extent the ability of resistant physicians to bill for the balance of nonassigned claims.<sup>80</sup>

The Medicare Utilization and Quality Peer Review Organizations ("PROs") are a second example of the Medicare/provider regulatory relationship. PROs, which regulate the utilization and quality of Medicare-financed services, have little contact with beneficiaries, dealing instead directly with providers. PROs review provider claims, determining whether claimed services were medically necessary, of acceptable quality, and provided in an appropriate setting. If a PRO decides to deny payment for services, it is the provider rather than the patient who must, in most instances, bear the cost of the denied services.<sup>81</sup>

As Medicare has transformed into a purchaser and regulator, however, HHS has remained remarkably faithful to the narrowest interpretation of its initial nonintervention promise by eschewing any significant direct regulatory role. HHS has chosen, rather, to carry out its manifold regulatory functions indirectly through the states and private regulators. Like many other federal regulatory programs that have emerged in recent decades, Medicare has often attempted to use preexisting state regulatory programs for its own purposes.<sup>82</sup> In some instances, this has simply meant that Medicare has relied on preexisting state regulatory programs for its own purposes, as it did when it required state licensure as a condition of physician reimbursement.<sup>83</sup> In other situations, the federal government has funded state programs that supplement parallel federal efforts, as is true with fraud and abuse programs.<sup>84</sup> In still other instances, where HHS operates its own regulatory programs, it has accepted parallel state regulation of providers as an alternative if, and only if, the state program meets stringent federal requirements, as is true with clinical laboratories.<sup>85</sup> In some cases, Medicare has contracted with the states to carry out federal regulatory responsibilities, as it does when the states validate Joint Commission accredita-

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80. PHYSICIAN PAYMENT REVIEW COMM'N, ANNUAL REPORT TO CONGRESS 5 (1991); John Holahan & Stephen Zuckerman, *Medicare Mandatory Assignment: An Unnecessary Risk*, HEALTH AFFAIRS, Spring 1989, at 65, 66-67.

81. See Timothy Stoltzfus Jost, *Policing Cost Containment: The Medicare Peer Review Organization Program*, 14 PUGET SOUND L. REV. 483, 511-12 (1991).

82. Precedents for reliance on state agencies in social insurance programs existed at the time Medicare was established, including the use of state agencies for determining disability for the social security disability program. MYERS, *supra* note 65, at 173.

83. 42 U.S.C. § 1395x(r) (1988).

84. See *id.* § 1396b(a)(6), (q) (establishing federal funding for state Medicaid fraud and abuse units).

85. 42 C.F.R. § 493.513(a)(1) (1992).

tion.<sup>86</sup> Finally, Medicare has in some cases directly and aggressively intervened to reshape a preexisting state regulatory program, as it did with nursing home regulation.<sup>87</sup>

Medicare has also relied on a variety of forms of private regulation. In a few instances, this has involved industry self-regulation. Joint Commission accreditation is one example of this, as is Medicare's requirement that hospitals conduct internal utilization reviews.<sup>88</sup> More often, Medicare has relied on private entities other than providers for regulation. Medicare carriers and intermediaries, private insurers or data processors, are delegated regulatory responsibility for policing the necessity and appropriateness of Medicare-financed services.<sup>89</sup> Medicare has also created specialized private (or quasi-public) regulatory bodies, the Medicare Peer Review Organizations, and then contracted with them to carry out specific PRO regulatory programs.<sup>90</sup>

Why has HHS rejected the options of state regulation or of creating independent, purpose-made private entities for regulating hospitals, choosing rather to continue to rely on industry self-regulation through the Joint Commission? First, Medicare's most favored alternative, reliance on state regulation, was not viable at the time of Medicare's creation in the mid-1960s, when state hospital licensure programs, most of which had been established in the preceding two decades, were weak and ineffectual.<sup>91</sup> Staffing levels were low, and enforcement was sporadic.<sup>92</sup> Though some state hospital licensure programs have improved over the years, reliance on state licensure today would merely constitute a less direct form of reliance on the Joint Commission, because so many states still rely heavily on the Joint Commission for determining licensure status.<sup>93</sup>

The PRO program could perhaps have taken the place of Joint Commission accreditation as Medicare's instrument for hospital regulation. Since its inception, however, the PRO program, like its predecessor the Professional Standards Review Organization ("PSRO") program,<sup>94</sup> has focused principally on individual patient encounters with the health care system rather than on institutions from a more global perspective. This is undoubtedly because the initial emphasis of the PSRO program, out of which the PRO program grew, was on utilization review, and utilization review in the United States has

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86. 42 U.S.C. § 1395aa(c) (1988); 42 C.F.R. § 488.6 (1992).

87. See Timothy S. Jost, *Legal Characteristics of the Extended Care Facility*, in *HEALTHCARE FACILITIES LAW* 993, 1006-17 (Anne M. Dellinger ed., 1991).

88. WITKIN, *supra* note 63, at 117-26.

89. 42 C.F.R. §§ 421.100, 421.200 (1992).

90. See 42 U.S.C. §§ 1320c to 1320c-13 (1988).

91. HILARY G. FRY, *THE OPERATION OF STATE HOSPITAL PLANNING AND LICENSURE PROGRAMS* 23-47 (1965); Milton I. Roemer, *Controlling and Promoting Quality in Medical Care*, 35 *LAW & CONTEMP. PROBS.* 284, 290 (Spring 1970); Worthington & Silver, *supra* note 23, at 308-10.

92. FRY, *supra* note 91, at 38, 43-46.

93. See *supra* note 16.

94. See 42 U.S.C. § 1320c-1 (1988).

historically focused on individual cases.<sup>95</sup> In this tradition, PROs have reviewed care on a case-by-case basis, subjecting cases to generic quality and discharge screens and scrutinizing only the individual cases selected by these screens for professional review.<sup>96</sup> PROs have generally not looked at the structural characteristics of hospitals and, until recently, rarely looked at process and outcome issues from an institution-wide perspective.

Very recently, the work of PROs and of the Joint Commission has begun to converge; PROs have begun to move under the Fourth Scope of Work (the document that defines PRO responsibilities for the three-year contract period beginning in 1993)<sup>97</sup> toward analysis of patterns of medical care based on the Uniform Clinical Data Set,<sup>98</sup> and the Joint Commission has focused more on process and outcome issues under the Agenda for Change.<sup>99</sup> Nevertheless, the two programs still remain largely complementary rather than redundant. Absent a major transformation and a significant increase in funding, PROs could not take over the function of the Joint Commission in certifying industry-wide compliance with Medicare participation conditions.

### C. Why Has HHS Not Taken Over Hospital Regulation Itself?

Even though no suitable external alternative to the Joint Commission has existed, HHS, or more specifically HCFA, could itself have taken over surveying hospitals for compliance with Medicare conditions of participation and made hospital participation in Medicare dependent on the result of its own surveys. Why has this not happened?

First, and most important, is the cost to HCFA of administering such a program. In 1991, HCFA estimated that it would cost \$59 million and require 722 additional full-time employees for it to assume responsibility for surveying all hospitals (including those currently granted deemed status) for Medicare compliance.<sup>100</sup> This would require increasing the size of HCFA by almost a third, as HCFA currently has a total of 1175 employees in the central office and 1049 in the regional offices administering the entire Medicare program.<sup>101</sup> HCFA currently has only five central office employees and a handful of additional regional office staff managing the Medicare hospital certification

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95. See Timothy Stoltzfus Jost, *Administrative Law Issues Involving the Medicare Utilization and Quality Peer Review Organization (PRO) Program: Analysis and Recommendations*, 50 OHIO ST. L.J. 1, 4-5 (1989).

96. *Id.* at 34-35.

97. See *A Welcome Move Toward PRO Reform*, AM. MED. NEWS, Nov. 16, 1992, at 29.

98. The Uniform Clinical Data Set is a computerized database which contains information about conditions and treatments from the medical records of about one million patients per year. Stephen F. Jencks & Gail R. Wilensky, *The Health Care Quality Initiative: A New Approach to Quality Assurance in Medicare*, 268 JAMA 900, 900-01 (1992).

99. See *id.* at 901-03 (discussing the new directions in which the PRO program is going).

100. GAO, *MONITORING*, *supra* note 36, at 25.

101. Telephone Interview with Sharon Goldburn, Personnel Management Specialist, HCFA (May 19, 1993).

program.<sup>102</sup> In particular, HCFA would have to hire, train, and maintain a staff of costly professionals, including physicians, nurses, and attorneys, to formulate and enforce program standards. Under Medicare amendments adopted in 1990 that bar user fees for survey and certification purposes, HCFA would have to absorb all of these costs itself.<sup>103</sup>

Of course, the present Joint Commission surveys are themselves quite expensive.<sup>104</sup> Medicare bears part of this cost because its payments to hospitals are still loosely based on historic aggregate hospital expenditures, which include accreditation costs.<sup>105</sup> However, since Medicare currently pays for only about twenty-seven percent of the cost of hospital care,<sup>106</sup> most of the cost of Joint Commission certification is borne by other payers. Moreover, because many states rely on Joint Commission certification for licensure and because hospitals may well seek the cachet of Joint Commission accreditation regardless of regulatory requirements, it is likely that hospitals would continue to pay for Joint Commission accreditation and to pass this cost on in part to Medicare regardless of any independent regulatory program HCFA might establish. Finally, it is arguable that the Joint Commission provides survey and certification services at a lower cost than HCFA could. To the extent, for example, that the Joint Commission can draw on the expertise of its member groups for assistance in formulating and interpreting standards, it may avoid some costs that HCFA would incur in operating a regulatory program.<sup>107</sup>

More than any other factor, the practical consideration of cost explains why Congress and HCFA have been content to rely on the Joint Commission

102. *Hospital Accreditation and Compliance with Medicare's Conditions of Participation: Hearings before the Subcomm. on Health of the House Comm. on Ways and Means*, 101st Congress, 2d Sess. 13 (1990) (statement of David P. Baine) [hereinafter *Hearings*]; *id.* at 25 (statement of Thomas Morford, Director, Health Standards and Quality Bureau).

103. 42 U.S.C. § 1395aa(e) (1988 & Supp. III 1991).

104. Laura Greanias, *Hospitals Find Probation by JCAHO Not as Bad as they had Imagined*, MOD. HEALTHCARE, July 1, 1991, at 26, 27 (basic, initial survey fee for a triennial survey in 1991 was \$6,052, but survey of a large university hospital might cost as much as \$40,000 to \$45,000 because of additional services to be surveyed); *Survey Fees to Cover Accreditation Process Costs*, JOINT COMMISSION PERSPECTIVES, Nov.-Dec. 1992, at 6 (base fee for 1993 is \$6,675). This is, of course, just the cost of the survey. The total costs of survey preparation are much higher. One hospital estimated its costs at \$326,784. Don A. Rockwell, *The Cost of Accreditation: One Hospital's Experience*, HOSP. & COMMUNITY PSYCHIATRY, Feb. 1993, at 151. Another hospital recently estimated that it spends about \$118,000 a year to maintain JCAHO accreditation. David Burda, *Hospital Exec Appeals to JCAHO to Consider Costs*, MOD. HEALTHCARE, May 23, 1994, at 12.

105. See TERRY S. COLEMAN, LEGAL ASPECTS OF MEDICARE & MEDICAID REIMBURSEMENT 28-34 (1990).

106. Katherine R. Levit et al., *National Health Expenditures, 1990*, HEALTH CARE FINANCING REV., Fall 1991, at 29, 52.

107. See *infra* text accompanying note 164 (discussing the Joint Commission's use of its Professional Technical Advisory Committees in standards setting). On the other hand, it is arguable that current JCAHO survey costs are ultimately passed on to consumers, who must also as taxpayers finance independent HCFA surveys; thus, society as a whole would save money by transferring the entire cost to the federal government. STIEBER & WOLFE, *supra* note 16, at 27-29. Whether in fact the total cost of certification would be less if the federal government took over this function remains an empirical question, the answer to which depends on how much a federal certification program would cost and whether hospitals would drop Joint Commission accreditation if such a program existed.

hospital accreditation program and why they have not developed their own hospital survey and certification program. A second reason, however, might offer a further explanation: the Joint Commission is better able than HCFA to adapt its standards to incorporate the rapidly developing technology of health care quality assessment and improvement.<sup>108</sup>

HCFA does in fact, as noted earlier, have its own conditions for hospital participation.<sup>109</sup> The first iteration of these standards, created in 1966 at the time Medicare was established, was based on the then-existing JCAHO standards and considered structural aspects of quality almost exclusively.<sup>110</sup> In 1977, HCFA undertook to update these standards.<sup>111</sup> Draft regulations were published in 1980,<sup>112</sup> and again in 1983, after a change of administration.<sup>113</sup> HCFA published final regulations in 1986<sup>114</sup> and has not revisited them since.

As evidenced by this history, updating federal provider conditions of participation has been a difficult and very time-consuming process. Not only is HCFA subject to the notice and comment constraints of the Administrative Procedure Act ("APA"),<sup>115</sup> but it has also in recent years been subject to close and prolonged scrutiny from the Office of Management and Budget.<sup>116</sup> When in the related area of nursing home regulation HCFA tried to gain flexibility not available under the APA by proposing broad standards as rules to be enforced through unpublished survey guidelines,<sup>117</sup> its position was decisively rejected

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108. The advantage that private standard-setting bodies enjoy over public ones in the areas of flexibility and responsiveness has been noted in other areas. Cheit notes that

[p]rivate standards-setting is prospective and ongoing, while public efforts tend to be corrective and singular. Private standards-setters tend to intervene relatively early in the life cycle of an issue, adjusting the subsequent standards over time. Public standards-setters, by contrast, are likely to get involved later in time, often after a major disaster, and to adopt a "one-shot" standard that is not later revised.

ROSS E. CHEIT, *SETTING SAFETY STANDARDS: REGULATION IN THE PUBLIC AND PRIVATE SECTORS* 19, 202-05 (1990); see also DOUGLAS C. MICHAEL, *FEDERAL AGENCY USE OF AUDITED SELF-REGULATION AS A REGULATORY TECHNIQUE* 10-12 (1993) (Preliminary Draft for the Administrative Conference of the United States) (to be published in 47 ADMIN. L. REV., No. 2 (1995)) (discussing the advantages of flexibility that attend self-regulation).

109. 42 C.F.R. §§ 482.1-66 (1993).

110. McGeary, *supra* note 17, at 301-04, 311.

111. *Id.* at 309.

112. 45 Fed. Reg. 41,794 (1980); see McGeary, *supra* note 17, at 310.

113. 48 Fed. Reg. 299 (1983); see McGeary, *supra* note 17, at 310. The second draft was rewritten to reflect JCAHO accreditation standards.

114. 51 Fed. Reg. 22,010 (1986) (codified at 42 C.F.R. §§ 482.1-66) (1992).

115. 5 U.S.C. § 553 (1988).

116. For example, the OMB tied up proposed rules implementing nursing home reform legislation for more than a year, and then only released the rules under pressure from consumer groups and congressional leadership. *Enforcement Rules Published*, QUALITY CARE ADVOCATE, July-Aug. 1992, at 1, 6. On OMB review of agency action generally, see Harold H. Bruff, *Presidential Management of Agency Rulemaking*, 57 GEO. WASH. L. REV. 533 (1989). Delay is a general problem affecting government standards-setting programs. See CHEIT, *supra* note 108, at 194; JOHN M. MENDELOFF, *THE DILEMMA OF TOXIC SUBSTANCE REGULATION* 106-39 (1988); John P. Dwyer, *The Pathology of Symbolic Legislation*, 17 ECOLOGY L.Q. 233, 258-60, 277-81 (1990).

117. 52 Fed. Reg. 24,752 (1987).



in federal court.<sup>118</sup> By contrast, the Joint Commission amends its standards annually and is currently undergoing a substantial rethinking of its entire body of certification standards. As the Director of HCFA's Health Standards and Quality Bureau acknowledged at a congressional hearing:

[P]rivate sector organizations don't need to issue proposed rules, final rules, et cetera, to deal with everybody in the country who has a better idea. They can go and pretty much set standards that are the state of the art. That is a big encumbrance for the government. We will never match private sector standards vis-a-vis the state of the art. That is why deeming in general terms is a fairly good notion.<sup>119</sup>

## V

### IS ACCREDITATION AN ACCEPTABLE ALTERNATIVE TO DIRECT REGULATION?

While considerations of cost-savings and of regulatory flexibility might explain why HHS has chosen to rely on Joint Commission accreditation for assuring quality in hospitals, the question remains open whether Joint Commission accreditation is adequate to protect the public's interest in quality health care. It is to this question that this article now turns, considering first theory and then the practical evidence.

#### A. Theoretical Considerations

In an earlier article, I developed at length a model for understanding the Joint Commission.<sup>120</sup> True self-regulation has been adopted in a number of industries for a variety of reasons, including forestalling government regulation and enhancing consumer confidence in products that consumers would otherwise have difficulty evaluating.<sup>121</sup> The Joint Commission is often characterized as a self-regulatory body, and, insofar as it includes the American Hospital Association among its members, it can be thought of in this way. Hospitals, however, do not usually think of the Joint Commission as "their" regulator. Hospital executives do not view it as a friendly, collegial presence, rather more commonly as a troublesome external regulator.<sup>122</sup> Indeed, surveys of hospital CEOs in recent years have found them quite critical of the Joint Commission.<sup>123</sup> In fact, the Joint Commission is better understood historically not as representing true self-regulation (that is, the hospital industry regulating itself),

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118. *Estate of Smith v. Bowen*, 675 F. Supp. 586, 590 (D. Colo. 1987).

119. *Hearings*, *supra* note 102, at 25 (statement of Thomas Morford).

120. Jost, *supra* note 3, at 860-80.

121. EUGENE BARDACH & ROBERT A. KAGAN, *GOING BY THE BOOK: THE PROBLEM OF REGULATORY UNREASONABLENESS* 220-23 (1982); CHEIT, *supra* note 108, at 179-80; Jost, *supra* note 3, at 868-71.

122. See, e.g., Michael Abramowitz, *On the Road with a Hospital Inspector: How Well Does A Private Agency Survey the Nation's Health Care Centers*, WASH. POST, Aug. 27, 1991, at Z8; Donna Ojanen Thomas, *How to Survive an Accreditation Review*, R.N., Apr. 1987, at 17; sources cited *infra* notes 154-56.

123. These polls are discussed further *infra* in the text accompanying notes 154-56.

but rather as representing what might be called cross-regulation, specifically regulation of the hospitals by their most immediate consumers—physicians.<sup>124</sup>

The Joint Commission grew out of the ACS's Hospital Standardization Program, a clear attempt by surgeons to standardize hospitals, which in the early twentieth century were far from acceptable as places to practice medicine.<sup>125</sup> Throughout its history, the majority of the commissioners of the Joint Commission have been doctors. As evidenced by articles in the medical trade association press, these commissioners represent the interests of their constituents as well as promote the mission of the Joint Commission.<sup>126</sup> The prerogatives of physicians in the governance of hospitals and their control over medical staff issues are jealously guarded by these members.<sup>127</sup> One would expect the Joint Commission, as a cross-regulatory program, to be very concerned with standardizing hospitals to assure their maximum utility to doctors, but to avoid at all costs closing hospitals and thus putting doctors out of work.

Neither of these models fully explains the behavior of the Joint Commission in the recent past, however. The Joint Commission has also become, paradoxically, a creation of the responsibilities that have been delegated to it. Though participation in the Joint Commission hospital accreditation program is still in theory voluntary, it would be very difficult for a sizeable hospital to forgo accreditation. Doing so would not only risk the public calling into question the quality of the services offered by the hospital, but would also endanger the hospital's federal Medicare status and, in many states, the hospital's licensure. The power, wealth, and status of the Joint Commission are dependent, therefore, upon its continued recognition by the public in general and the federal and state government in particular as an acceptable regulator. The Joint Commission has thus increasingly come to resemble other private standard-setters, which pursue their own interests as guarantors of quality to some extent independent of the more narrow interests of their sponsoring organizations.<sup>128</sup>

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124. See Jost, *supra* note 3, at 865-69; see also DAVID HEMENWAY, *INDUSTRY-WIDE VOLUNTARY PRODUCT STANDARDS* 63-68, 74-76 (1975) (offering examples of cross-regulation in other industries).

125. Jost, *supra* note 3, at 845-49; Carl P. Schlicke, *American Surgery's Noblest Experiment*, 106 *ARCHIVES SURGERY* 379, 379-80 (1973).

126. See Brian McCormick, *Trustees Reverse Stance on Joint Commission Participation*, 34 *AM. MED. NEWS*, Dec. 23/30, 1991, at 4-5 [hereinafter McCormick, *Trustees*] (AMA House of Delegates criticizes Joint Commission's quality initiatives and questions whether AMA should continue to participate in Joint Commission); Brian McCormick, *HMSS Tackles Practice Parameters, Joint Commission*, 34 *AM. MED. NEWS*, July 8, 1991 at 17 (AMA Joint Commission members champion AMA Hospital Medical Staff Section's position on protecting medical staff autonomy) [hereinafter McCormick, *HMSS*].

127. See McCormick, *Trustees*, *supra* note 126; McCormick, *HMSS*, *supra* note 126; Brian McCormick, *House Backs Continued Practice Parameter Role*, 33 *AM. MED. NEWS*, Dec. 14, 1990, at 8.

128. See CHEIT, *supra* note 108, at 16, 176-87 (noting that in other arenas private standard-setters are able to pursue a more independent course where they receive government support or recognition).

The Joint Commission's recently adopted policy of performing unannounced inspections on five percent of accredited facilities annually<sup>129</sup> can best be understood under this independent regulator model. This policy enhances the Joint Commission's legitimacy as a regulator but runs counter to the interests of its accredited institutions, which would undoubtedly prefer announced inspections that allow them to showcase their institutions.<sup>130</sup>

Finally, the Joint Commission seems to be positioning itself to assume still another role. The Joint Commission has recently established a program for accrediting health care provider networks.<sup>131</sup> It has also committed itself to modify its information disclosure policy so as to provide consumers with substantially more information regarding accredited institutions.<sup>132</sup> The Joint Commission obviously seems to be preparing itself for a reformed health care system based on competition among health care networks.<sup>133</sup> In such a system, consumers will badly need information regarding the comparative quality of both health care institutions and health care networks. If the Joint Commission can establish itself as a credible source of such information, it may in the future find that its primary customers are not the institutions it accredits, the doctors who work in those institutions, or the government, but rather the consumers of health care and their institutional agents (such as health alliances). Under these circumstances, the Joint Commission could become an agent and adviser of purchasers.

Under any of these models, the Joint Commission could be expected, for varying reasons, to make some contribution toward assuring the quality of care in hospitals. In its self-regulatory role, it could be expected to pursue a strategy of creating and enforcing standards sufficiently stringent to maintain consumer confidence and forestall further regulatory intervention, making a special effort to deal aggressively with hospitals in which conditions are bad enough to give the whole industry a bad name.<sup>134</sup> On the other hand, if it were merely a self-regulator, the Joint Commission would be unlikely to provide information to

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129. See Dennis S. O'Leary, *Unannounced Surveys: A Positive Force*, JOINT COMMISSION PERSPECTIVES, Jan./Feb. 1993, at 2.

130. See Linda Oberman, *supra* note 1, at 6.

131. See JOINT COMMISSION STANDARDS, *supra* note 10.

132. See Linda Oberman, *Top Accreditor Goes Public on New Hospital Report Cards*, AM. MED. NEWS, Oct. 10, 1994, at 3; Andrew Skolnick, *Joint Commission Will Collect, Publicize Outcomes*, 270 JAMA 165 (1993); see also Joint Comm'n on Accreditation of Healthcare Orgs., *Joint Commission Prepares for Release of Organization-Specific Performance Data: Expands Policy on Falsification of Information*, May 17, 1993 (news release, copy on file with author); Mary T. Koska, *JCAHO Gets Lukewarm Reviews From its CEO Opinion Survey*, 64 HOSPITALS, May 5, 1990, at 49.

133. See *Consumer Issues: Hearings on Health Care Reform (Part 4) Before the Subcomm. on Commerce, Consumer Protection, and Competitiveness of the House Comm. on Energy and Commerce*, 103d Cong., 1st Sess. (1993) (statement of Dennis S. O'Leary, President, Joint Commission on Accreditation of Healthcare Organizations).

134. See Abramowitz, *supra* note 122, at Z8 (quoting a Joint Commission inspector as stating, "The only response we have to the people who want to take over the medical system may be to prove that we are monitoring ourselves"); see also Charles D. Bankhead, *Time is Running Out on Self-Policing Quality of Care: With Regulatory Groups Waiting in the Wings, the Medical Profession Can't Afford to Drag its Heels*, MED. WORLD NEWS, May 9, 1988, at 32.

consumers regarding quality differences among accredited institutions or to enforce standards rigorously against institutions in which quality lapses were not sufficiently serious to cause public scandal.<sup>135</sup>

As a cross-regulatory body, protecting the interests of physicians within hospitals, the Joint Commission could be trusted to assure that the structure, equipment, and staffing of hospitals are optimal for facilitating the work of physicians.<sup>136</sup> To the extent patients are primarily dependent on physician care within hospitals, the Joint Commission would protect the interests of patients.<sup>137</sup> Insofar as patients could benefit from nonphysician care within hospitals, however, the Joint Commission could play an anticompetitive role that would run counter to the patient's interest.<sup>138</sup>

As an independent private regulator, the Joint Commission could be expected to respond to political pressure for an enhanced regulatory presence and to rapidly incorporate technical and professional developments in quality assessment, assurance, and improvement. It could be expected to develop its own culture and commitment to quality assurance, to some extent independent of the interests of its member organizations.<sup>139</sup>

Finally, as a consultant to purchasers, the fortunes of the Joint Commission turn on its ability to provide trustworthy information regarding health care institutions and networks. It could be expected to devote itself to developing and implementing reliable instruments for assessing quality.

All four roles of the Joint Commission are consistent with its Agenda for Change, which represents a significant attempt to enhance the ability of hospitals to assess and improve quality. The Joint Commission's Agenda for

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135. See Koska, *supra* note 132, at 46 (reporting that hospital CEOs are concerned about hospital-specific data releases by Joint Commission). Cheit notes that private standards-testers may be able to push firms marketing products below generally accepted standards to improve their performance, but must follow the average firms in the determination of what is generally acceptable. CHEIT, *supra* note 108, at 183.

136. See Emily Friedman, *Accreditation Redesign Evolving*, 30 MED. WORLD NEWS, June 26, 1989, at 24 (citing difficulty Joint Commission had rewriting its standards because of "turf" issues). "Dr. O'Leary [the president of the Joint Commission] thinks that many existing Joint Commission standards involve 'guild issues' that are dear to health care professionals but not necessarily relevant to the quality of care." *Id.* at 35. The classic example of such issues is that of the independence of the medical staff and their role in governance of hospitals.

137. Cheit notes that in other private standard setting contexts other advocates of consumer interests emerge, such as insurers or vendors of safety or pollution control equipment. CHEIT, *supra* note 108, at 177.

138. See CLARK C. HAVIGHURST, *HEALTH CARE LAW AND POLICY* 648-51 (1988); Jost, *supra* note 3, at 908-10; Brian McCormick, *Nurses Vow to Fight On for Joint Commission Representation*, AM. MED. NEWS, Nov. 2, 1990, at 5 (American Nursing Association denied position on Joint Commission Board).

139. See McCormick, *Trustees*, *supra* note 126; McCormick, *HMSS*, *supra* note 126 (AMA Commissioners voted down by other commissioners on some AMA positions, but working together with others to promote those positions); Brian McCormick, *AMA Not Ready for New Quality Philosophy*, 34 AM. MED. NEWS July 22, 1991, at 5 (AMA Delegate resolutions question JCAHO quality initiatives and urge protection of physician prerogatives in hospitals); see also CHEIT *supra* note 108, at 16, 178-79; JOSEPH V. REES, *REFORMING THE WORKPLACE* 103-05, 226-27 (1988) (noting similar phenomena in other regulatory settings).

Change also makes sense if placed in the context of the wider federal health policy debate. In recent years, it has become clear that the U.S. health care system has failed miserably in terms of making affordable health care universally available. By measures of cost and access, the U.S. health care system compares poorly to the systems of all other industrialized nations.<sup>140</sup> This leaves both health care professionals and institutional providers with one argument, in fact heard repeatedly, "We have the best health care in the world."<sup>141</sup> To the extent that the Joint Commission adds credence to this argument by keeping at the forefront of innovation in defining, measuring, and improving quality, it advances the cause of the entire U.S. health care industry.<sup>142</sup>

The Joint Commission's recent emphasis on continuous quality improvement makes it possible for it to pursue quality aggressively without threatening providers or physicians. The continuous quality improvement strategy emphasizes the internal identification and solution of problems rather than the external enforcement of standards; the improvement of processes rather than the elimination of problem personnel; and incentives rather than sanctions. The strategy is thus a much more acceptable form of quality improvement than traditional inspection and sanction strategies.<sup>143</sup> To the extent the continuous quality improvement strategy is effective, the Agenda for Change bodes well for consumers as well as for the industry.

## B. Evidence of the Joint Commission's Performance

There is remarkably little evidence as to whether Joint Commission accreditation in fact assures the quality of hospital care. Few studies exist correlating Joint Commission accreditation status with other measures of hospital quality. One study of state psychiatric hospitals that compared accreditation status with characteristics described as quality of care indicators found that median values for these measures were higher in accredited than in nonaccredited hospitals.<sup>144</sup> Another study, however, has failed to find statistically significant relationships between Joint Commission accreditation

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140. See Robert G. Evans, *Tension, Compression and Shear: Directions, Stresses and Outcomes of Health Care Cost Control*, 15 J. HEALTH POL., POL'Y & L. 101 (1990).

141. See, e.g., James S. Todd et al., *Health Access America: Strengthening the U.S. Health Care System*, 265 JAMA 2503, 2503 (1991) (outlining the AMA's health reform plan and stating in introduction: "We have become the premier nation in providing high-quality, comprehensive medical care and education.").

142. See Abramowitz, *supra* note 122, at Z8 (quoting Joint Commission president Dennis O'Leary as stating: "We're not going to solve the problem of spiraling health care costs. But purchasers of health care will know in the future what they're buying. They'll know what they're getting in value.").

143. See DONALD M. BERWICK ET AL., *CURING HEALTH CARE: NEW STRATEGIES FOR QUALITY IMPROVEMENT* (1990); Donald M. Berwick, *Continuous Improvement as an Ideal in Health Care*, 320 NEW ENG. J. MED. 53 (1989); Stephen B. Kritchevsky & Bryan P. Simmons, *Continuous Quality Improvement: Concepts and Applications for Physician Care*, 266 JAMA 1817 (1991).

144. Martin C. McGurrian & Trevor R. Hadley, *Quality of Care and Accreditation Status of State Psychiatric Hospitals*, 42 HOSP. & COMMUNITY PSYCHIATRY 1060, 1061 (1991).

status and hospital mortality information published by HCFA.<sup>145</sup> Finally, the Harvard Medical Practice study, reviewing a weighted random sample of 43,429 medical records from fifty-one randomly selected New York hospitals, failed to find a significant correlation between the number of deficiencies found to require corrective action by Joint Commission surveys from 1984 and 1986 and the rate of adverse events or the rate of negligently caused adverse events found in the hospitals in 1984.<sup>146</sup> The study also failed to find a correlation between the rate of JCAHO-identified deficiencies and either a risk-adjusted patient mortality index or a risk-adjusted thirty-day unexpected patient readmission index.<sup>147</sup> None of these studies is definitive.

In the absence of empirical research, other measures of performance can be considered. One such measure is the evaluation of Joint Commission accreditation by its various constituencies. Consumer groups and journalists have often criticized the deemed status program, usually citing anecdotal situations in which the Joint Commission granted accreditation to hospitals in which truly dreadful conditions existed.<sup>148</sup> The most widely publicized of such critiques was an article by Walt Bogdanich in the *Wall Street Journal* in 1988.<sup>149</sup> The fact that historically so few hospitals have lost accreditation status is customarily cited by such critiques as demonstrating the ineffectiveness of Joint Commission accreditation.<sup>150</sup> Some consumer groups, moreover, consider industry self-regulation to be inherently unacceptable, whatever its results.<sup>151</sup>

Accredited hospitals are also not wholly satisfied with the Commission's performance. In 1990 and 1991 surveys, hospital CEOs expressed concern regarding vague and inconsistently interpreted standards, unqualified or

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145. William F. Jessee & Catherine M. Schranz, *Medicare Mortality Rates and Hospital Quality: Are They Related?*, 2 QUALITY ASSURANCE IN HEALTH CARE 137 (1990). This study may, of course, indicate either that HCFA's mortality data or Joint Commission accreditation, or both, are faulty as measures of quality. See also OFFICE OF TECHNOLOGY ASSESSMENT, U.S. CONGRESS, THE QUALITY OF MEDICAL CARE: INFORMATION FOR CONSUMERS 197-200 (1988) (discussing the paucity of research on the validity and reliability of Joint Commission accreditation as a measure of quality).

146. Both indices were developed based on discharge abstract data from all 722,824 patients discharged from the 51 hospitals in 1984. Helen R. Burstin et al., *Correlations Between Different Measures of Hospital Quality* (1992) (abstract presented at the 1992 Annual Meeting of the Society of General Internal Medicine) (copy on file with author).

147. *Id.*

148. See, e.g., Martin Gottlieb, *Ideas & Trends, Accreditation; Questions at the Top on Health Policy*, N.Y. TIMES, May 17, 1992, § 4, at 18. While the National Committee to Preserve Social Security and Medicare has not taken a position on the deemed status program for hospitals, they are hesitant to support deemed status for Joint Commission-accredited nursing homes and home health agencies. Letter from Martha M. Mohler, National Committee to Preserve Social Security and Medicare, to Timothy S. Jost (June 11, 1993) (on file with the author).

149. Walt Bogdanich, *Small Comfort: Prized by Hospitals, Accreditation Hides Perils Patients Face; Slipshod Institutions Keep Groups's Seal of Approval Even in Forced Closings*, WALL ST. J., Oct. 12, 1988 at A1.

150. *PMS Calls for Federal Investigation*, 11 PEOPLE'S MED. SOC'Y NEWSL. (People's Medical Soc'y, Washington, D.C.), Feb. 1992, at 1; *JCAHO Accreditation Brands Hospitals Safe. . . But are They?*, 48 PEOPLE'S MED. SOC'Y NEWSL. (People's Medical Soc'y, Washington, D.C.), Feb. 1989, at 1.

151. See STIEBER & WOLFE, *supra* note 16, at 29-31; *JCAHO Slow to Change*, 12 PEOPLE'S MED. SOC'Y NEWSL. (People's Medical Soc'y, Washington, D.C.), April 1993, at 4; *The Way JCAHO Works*, PEOPLE'S MED. SOC'Y NEWSL. (People's Medical Soc'y, Washington, D.C.), Feb. 1989, at 5.

improperly trained inspectors, delays in processing survey reports, and difficulty in understanding survey reports.<sup>152</sup> The American Hospital Association has also released a report critical of the Joint Commission hospital survey process, primarily because of its high cost.<sup>153</sup> While complaints by accredited providers that an accreditation program is too stringent might give cause for consumer confidence in the accreditor, complaints of vagueness, high cost, and inefficiency do little to reassure consumers. Hospitals became increasingly vocal in 1994, complaining about the Joint Commission's proposals for using clinical indicators and for publishing hospital ratings, and about the quality of the survey process itself.<sup>154</sup> Several state hospital associations, as well as an association of Catholic hospitals, have expressed complaints or concerns regarding the Joint Commission in recent months, and in a widely publicized case, one hospital that had been accredited for forty years dropped its accreditation.<sup>155</sup> On the other hand, about two-thirds of health care executives surveyed by the Joint Commission in 1993 said that its performance had improved over the last five years, while only eight percent believed its performance was getting worse.<sup>156</sup>

State survey agencies report both advantages and disadvantages of relying on Joint Commission accreditation for licensure. In a recent survey of state licensure agencies, thirty-seven states reported benefits, with nine states reporting more than one benefit; forty-five states reported drawbacks, with twenty-six reporting more than one.<sup>157</sup> Benefits frequently reported included cost savings, national uniformity of standards, and reduction of duplication in surveys.<sup>158</sup> Drawbacks frequently reported included the infrequency of JCAHO surveys, loss of input and oversight control by the states, failure of the Joint Commission to ensure that standards were met, and the Joint Commission's educational (as opposed to regulatory) approach to certification.<sup>159</sup> In general, states that relied fully on the Joint Commission for licensure tended to report more benefits, while those that did not rely on the Joint Commission tended to report more drawbacks.<sup>160</sup>

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152. David Burda, *JCAHO Gets Better Grades from Chief Execs*, MOD. HEALTHCARE, May 13, 1991, at 7; *JCAHO Continues to Labor Under Criticism*, ALCOHOLISM & DRUG ABUSE WEEK, Apr. 18, 1990, at 4.

153. David Burda, *AHA Criticizes JCAHO*, MOD. HEALTHCARE, Sept. 29, 1989, at 5.

154. Burda, *supra* note 20, at 30; David Burda, *AHA Taking Close Look at Accreditation*, MOD. HEALTHCARE, Apr. 18, 1994, at 3.

155. B. Rhonda Bergman, *The Trials of Accreditation*, HOSPS. & HEALTH NETWORKS, Sept. 5, 1994, at 42; David Burda, *Meeting With La. Hospital Execs is Latest Stop for JCAHO's O'Leary*, MOD. HEALTHCARE, June 27, 1994, at 52; David Burda, *Catholic Systems Seek Changes at JCAHO*, MOD. HEALTHCARE, May 9, 1994, at 6; David Burda, *HANYS Studying Accreditation Needs*, MOD. HEALTHCARE, Apr. 25, 1994, at 22; Burda, *supra* note 20, at 30; John Morrissey, *Ark. Hospital Forgoes JCAHO*, MOD. HEALTHCARE, May 2, 1994, at 4.

156. David Burda, *Execs' Opinion of JCAHO Slips*, MOD. HEALTHCARE, May 30, 1994, at 6. The positive ratings were down from 75% and the negative ratings were up from 3% in 1992.

157. STIEBER & WOLFE, *supra* note 16, at 12-13.

158. *Id.*

159. *Id.*

160. *Id.* at Tables 4 and 5.

Though a number of GAO reports critical of the Medicare hospital certification process have appeared in recent years, they have tended to criticize problems in HCFA's own certification process or in its validation of the Joint Commission process, rather than to criticize the Joint Commission itself.<sup>161</sup> In addition, while congressional criticism of the deemed status program appears from time to time,<sup>162</sup> proposals continue to surface in Congress for expanding reliance on Joint Commission accreditation as a benchmark of hospital quality,<sup>163</sup> and Joint Commission accreditation of hospitals is commonly referred to as a mark of distinction in congressional remarks praising health professionals or institutions.<sup>164</sup>

The Joint Commission has often played a leading role in encouraging progressive change in the health care industry. Examples of recent reform-motivated additions to Joint Commission accreditation standards include requirements that hospitals institute policies to improve communication with non-English speaking patients,<sup>165</sup> to identify and protect victims of child, domestic, or elder abuse,<sup>166</sup> and to prohibit smoking in hospitals.<sup>167</sup> The Agenda for Change, of course, is the most prominent example of this leadership role.

In sum, though the Joint Commission has its critics, it continues to enjoy widespread, if not unanimous, support in its regulatory role and seems likely to continue its regulatory function in the foreseeable future. Nevertheless, there is room for improvement in the Medicare-Joint Commission relationship. It is to concerns about this relationship that this article now turns.

## VI

### ADDRESSING CONCERNS REGARDING THE MEDICARE-JOINT COMMISSION RELATIONSHIP

One initial concern regarding the Medicare-Joint Commission relationship involves the lack of politically accountable standards for governing Medicare hospitals. As noted above, there is a growing divergence between the federal Medicare conditions of participation and Joint Commission accreditation standards. This gap is largely explained by the fact that Joint Commission standards are continually updated while the federal participation condi-

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161. See sources cited *supra* note 36.

162. See, e.g., 136 Cong. Rec. E2465 (daily ed. July 24, 1990) (statement of Rep. Stark).

163. See, e.g., Indian Health Amendments Act of 1992, Pub. L. No. 102-573, § 706(c), 106 Stat. 4526, 4577 (codified at 25 U.S.C. § 1665e).

164. See, e.g., 138 Cong. Rec. E1791 (daily ed. June 12, 1992) (statement of Rep. Montgomery); 138 Cong. Rec. E695 (daily ed. March 17, 1992) (statement of Rep. Elton Gallegly); 137 Cong. Rec. E3839 (daily ed. Nov. 14, 1991) (statement of Rep. Lehman).

165. See Leigh Page, *Lost in the Translation; Medicine is Grappling with a Surge of Patients who Don't Speak English*, AM. MED. NEWS, Feb. 1, 1993, at 25, 26.

166. Teri Randall, *AMA, Joint Commission Urges Physicians Become Part of Solution to Family Violence Epidemic*, 266 JAMA 2524, 2524 (1991).

167. See Michael C. Fiore, *Smoke-Free Hospitals: A Time for Universal Action*, 102 CHEST 1317, 1317-18 (1992).



tions—which reflect Joint Commission standards of a decade ago—are not. Nonetheless, it is disquieting to some that hospitals participating in the Medicare program are largely being regulated under private standards that are only tenuously related to standards created under the publicly accountable process of notice and comment rulemaking.<sup>168</sup>

One solution to this problem would be to declare the Joint Commission a public agency, governed by the APA.<sup>169</sup> This would likely, however, subject the Joint Commission to the same regulatory paralysis that characterizes HCFA. Moreover, it is probably unnecessary. The Joint Commission, in fact, has its own internal notice and comment policy. Joint Commission standards are developed by task forces of experts acting under the supervision of the Board of Commissioners' Standards and Survey Procedures Committee and of the appropriate Professional and Technical Advisory Committee, each of which contains expert representatives of professional groups and at least one public member.<sup>170</sup> Draft standards that emerge from these committees are subjected to a "field review" by practitioners, provider organizations, government representatives, consumers, and persons representing regulated entities.<sup>171</sup> Standards are then tested for twelve to eighteen months prior to their full implementation. While this process may not include all of the interest groups that would participate in notice and comment rulemaking, it does assure some public input.

Rather than subjecting the Joint Commission to APA requirements, a better approach might be for HCFA itself to publish in the *Federal Register* a notice of new Joint Commission standards on which deemed status is based.<sup>172</sup> If policies were published at the time the Joint Commission submits its standards for field review, interested parties would be able to make their opposition to proposed policies known to the Joint Commission, Congress, and HCFA. Since HHS retains residual power to adopt standards more stringent than JCAHO requirements, it could in the face of sufficient public concern, initiate its own rulemaking procedures to override Joint Commission standard changes.

A second concern centers on the Joint Commission's enforcement abilities. While the concern about the accountability of Joint Commission standards is largely theoretical, the performance of the Joint Commission in the area of survey and enforcement has provoked more real controversy. It is a simple fact

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168. See, e.g., GAO, MONITORING, *supra* note 36, at 7-8.

169. See Jost, *supra* note 3, at 886-92.

170. See JOINT COMMISSION, *supra* note 2, at 17, 35-36; see also Roberts et al., *supra* note 3, at 939.

171. Roberts et al., *supra* note 3, at 939. Private standard-setting bodies often have procedures to encourage broad participation in setting standards. See CHEIT, *supra* note 108, at 216-18.

172. Compare procedures created by the Omnibus Budget Reconciliation Act of 1987 for publishing policies affecting the PRO program. 42 U.S.C. § 1320c-2(h)(i) (1988) ("The Secretary shall publish in the Federal Register any new policy or procedure adopted by the Secretary that affects substantially . . . the performance of [PRO contract obligations] not less than 30 days before the date on which such policy or procedure is to take effect.").

that the Joint Commission rarely denies or revokes accreditation.<sup>173</sup> It is also true that the HCFA validation process continues to identify hospitals that have retained accreditation despite serious shortcomings. This should not be surprising. It is obviously not in the interests of either the Joint Commission or its members to get the reputation of an aggressive enforcer, frequently subjecting mediocre facilities to the embarrassment of accreditation termination.<sup>174</sup> Nevertheless, it is questionable whether government regulation would be any more effective.

Here a word needs to be said about the HHS validation process. State survey agencies, as noted earlier, regularly survey a sample of Joint Commission-accredited hospitals to validate Joint Commission findings.<sup>175</sup> HCFA must report annually to Congress the results of its validation surveys.<sup>176</sup> The most recent report, for the fiscal years 1991 and 1992, concluded, as it had in its previous reports, that "in general, Joint Commission accreditation does, in fact, provide reasonable assurance that accredited hospitals meet Federal requirements."<sup>177</sup>

HCFA reached this conclusion despite the fact that its validation surveys regularly find a high number of accredited hospitals out of compliance with the Medicare standards of participation at the time of the validation survey. In 1992, fifty-seven of the 167 accredited hospitals (34%) subjected to a validation survey did not meet one or more Medicare conditions of participation. Many of the problems HCFA discovered had already been noted by the Joint Commission, however. The validation report concluded that the Joint Commission enforced some standards, such as quality assurance and infection control, more vigorously than the state survey agencies that perform validation surveys, whereas the state survey agencies enforced others, most notably life safety requirements, more vigorously than the Joint Commission.<sup>178</sup> In sum, HCFA concluded that JCAHO and state survey results were equivalent. HCFA has also reached this conclusion in reports from previous years.<sup>179</sup>

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173. See 1 INSTITUTE OF MEDICINE, *MEDICARE: A STRATEGY FOR QUALITY ASSURANCE* 129 (Kathleen N. Lohr ed., 1990); *Full Survey Decision Outcomes*, JOINT COMMISSION PERSPECTIVES, July-Aug. 1991, at 16.

174. It is also not always clear that the public would be better served by termination of deficient hospitals where the alternative is a significant curtailment of access to hospital care in rural or inner-city areas.

175. 42 U.S.C. § 1395aa(c) (1988); 42 C.F.R. § 488.6 (1993). Currently, approximately 200 accredited facilities are surveyed each year, including 125 that are surveyed within 60 days of the Joint Commission accreditation survey, about 50 that are surveyed 18 months into the accreditation survey, and about 25 that were conditionally accredited by the Joint Commission. Telephone Interview with Rachel Weinstein, Health Insurance Specialist, HCFA, (Mar. 3, 1993, Mar. 5, 1993) [hereinafter Weinstein Interview].

176. 42 U.S.C. § 1395ll(b) (1988).

177. HEALTH CARE FIN. ADMIN., DEP'T OF HEALTH AND HUMAN SERV., *REPORT ON MEDICARE VALIDATION SURVEYS OF HOSPITALS ACCREDITED BY THE JOINT COMMISSION ON ACCREDITATION OF HEALTHCARE ORGANIZATIONS (JOINT COMMISSION), FISCAL YEAR 1991 AND FISCAL YEAR 1992* 63 (1992) [hereinafter HCFA REPORT].

178. *Id.* at 64.

179. GAO, *CRITERIA*, *supra* note 36, at 5, 6.

Though the primary purpose of the validation survey process is to test the validity of the Joint Commission survey process, validation surveys are also used for enforcement purposes. A facility determined by a validation survey to be out of compliance with one or more conditions of participation and to have a significant deficiency will no longer be deemed to meet the conditions of participation.<sup>180</sup> If conditions in the facility jeopardize the health and safety of patients or seriously limit the provider's capacity to render adequate care, the facility is subject to fast track termination.<sup>181</sup> If conditions are deficient, but not this serious, the facility must submit a correction plan and achieve compliance within a reasonable period of time, usually sixty days.<sup>182</sup> Alternatively, a deficient facility can remain in deemed accreditation status if (1) the accrediting body accepts the state survey agency's finding of deficiencies and agrees to monitor correction of the deficiencies within a specified time frame, (2) the state is unable to justify to HCFA the need for continued review by the state survey agency to assure correction, and (3) the accrediting body provides HCFA with periodic reports of progress toward correction.<sup>183</sup> An accredited hospital dissatisfied with the results of a validation survey can request an informal review from HCFA within fifteen days.<sup>184</sup> Deemed status will be reinstated once HCFA finds that the hospital meets all Medicare conditions of participation.<sup>185</sup>

HCFA's enforcement program has in fact been neither more aggressive nor more effective than that of the Joint Commission. Under its current arrangements with the Joint Commission, HCFA does not learn that the Joint Commission has identified a hospital as having sufficiently serious problems as to justify conditional accreditation until four months or more after the accreditation survey.<sup>186</sup> Once the Joint Commission notifies HCFA of a problem in an accredited facility, HCFA must, if it chooses to terminate the facility, build its own termination case, duplicating the Joint Commission's effort. HCFA rarely goes through this process. Though thirty-five percent of accredited hospitals were given termination notices by HCFA during the

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180. A facility that refuses to cooperate with a validation survey is no longer deemed to meet Medicare certification requirements and can be terminated by Medicare. 42 C.F.R. § 488.6(c) (1993).

181. *Id.* § 489.53(b)(2) (1993).

182. *Id.* § 488.28 (1993).

183. *Id.* § 488.6(d)(2).

184. *Id.* § 488.6(f).

185. *Id.* § 488.6(e)(4). HCFA also contracts with state survey agencies to investigate complaints that allege noncompliance with conditions of participation in accredited facilities. 42 U.S.C. § 1395aa(c) (1988). If the problems alleged do not rise to the level of noncompliance with conditions of participation, HCFA will forward the complaint to the Joint Commission and notify the complainant that the complaint has been forwarded. Weinstein Interview, *supra* note 175.

186. Telephone interview with Terry Harris, Health Insurance Specialist, HCFA (Mar. 5, 1993). In 1989, when congressional hearings were held the delay was 15 months. See *Hearings, supra* note 102, at 3, 28 (statement of Gail R. Wilensky). This delay was clearly unacceptable to HHS. See Charles D. Bankhead, *Performance Complaints Bring JCAHO Under Scrutiny*, MED. WORLD NEWS, Oct. 1990, at 14.

validation process in FY 1992, none were in fact terminated from Medicare.<sup>187</sup> Indeed, facilities that have had their accreditation revoked by the Joint Commission have on occasion subsequently been certified to participate in Medicare by HCFA after a state survey.<sup>188</sup>

In sum, then, validation surveys regularly identify significant deficiencies in accredited facilities, but these facilities are rarely decertified by HCFA.<sup>189</sup> Given the paucity of HCFA's resources and its historical lack of interest in enforcement, this is not surprising. Unfortunately, the absence of state and federal enforcement actions against hospitals leaves little room for hoping that the public would be substantially better served by direct federal regulation of hospitals than by Joint Commission regulation. Moreover, as the Joint Commission has in recent years moved toward a variety of levels of accreditation and toughened up its enforcement by requiring most hospitals to clear up deficiencies following the survey,<sup>190</sup> the advantage that a public enforcement program may have at one time enjoyed over Joint Commission accreditation has diminished.<sup>191</sup> Neither approach to quality evaluation seems clearly superior from the standpoint of enforcement.

Though the argument for substituting a public regulatory program for the current Joint Commission/public regulation partnership is weak, the effectiveness of the current arrangement could be improved by better targeting HHS's validation effort. Targeting the validation effort upon conditionally accredited hospitals was a good first step in this direction. Surveys could be targeted further at hospitals identified by PROs as being problem facilities or hospitals with extraordinarily high risk-adjusted mortality rates. Timing of validation surveys might also be important. HCFA's recent efforts to conduct validation surveys at the midpoint of the JCAHO survey cycle has resulted in the finding of substantially more violations.<sup>192</sup> Finally, validation surveys could focus on certain standards, such as fire safety code compliance, on which the Joint Commission puts less emphasis. Targeting of this kind might result in more stringent regulation of problem hospitals.

A third concern regarding the Medicare-Joint Commission relationship is the inability of the Joint Commission to deal with regulatory concerns other than quality. The original Medicare statute required deemed status hospitals to meet a separate federal requirement for utilization review, which was then absent

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187. HCFA REPORT, *supra* note 177, at 59, 62.

188. INSTITUTE OF MEDICINE, *supra* note 173, at 129; *Hearings*, *supra* note 102, at 22-24.

189. See GAO, INADEQUATE, *supra* note 36, at 3.

190. See Mary T. Koska, *JCAHO: Safety, Medical Staff Issues Hinder Compliance*, HOSPITALS, Apr. 5, 1992, at 46 (during 1987-89, two-thirds of the nation's hospitals were subject to accreditation contingencies).

191. In fact, most public enforcement programs rely, like the Joint Commission, on prodding compliance rather than rigidly imposing sanctions. See Keith Hawkins & John M. Thomas, *The Enforcement Process in Regulatory Bureaucracies*, in ENFORCING REGULATION 3 (Keith Hawkins & John M. Thomas eds., 1984).

192. HCFA REPORT, *supra* note 177, at 63.

from Joint Commission requirements.<sup>193</sup> Though the Joint Commission subsequently adopted a utilization review requirement, and though the Joint Commission's emergency care standards have played a positive role in assuring access to health care for indigents,<sup>194</sup> the Joint Commission has not taken the lead in assuring access or cost control. Nor could it, given its need to be responsive to its members. Indeed, as cost control issues come to the fore, people may increasingly question whether Joint Commission standards in fact lead to excessive costs in the provision of hospital care.

The Joint Commission was earlier identified as partly a cross-regulation program—as doctors regulating hospitals. Other cross-regulatory interventions in health care are also conceivable, however. Most notably, health insurers could sponsor accreditation entities, attuned particularly to standards that would lower cost, while preserving acceptable, if not optimal, quality. The National Committee for Quality Assurance, for example, which accredits HMOs, includes on its twelve-member board employee benefits managers, consumer advocates, and labor leaders, and is seeking support from major employers.<sup>195</sup> To maintain its competitive position or to become more responsive to health care purchasers, the Joint Commission may in the end have to consider cost of care as well as quality in establishing and enforcing its accreditation standards. In the interim, complementary regulatory approaches are necessary to address cost and access problems.

A fourth and final concern is whether the federal government, by relying on the Joint Commission for regulating hospitals, has endorsed too narrow and monolithic a vision of health care, thereby unreasonably limiting patient choice. Professor Clark Havighurst has on several occasions articulated the view that a multiplicity of accreditors is necessary to facilitate consumer choice, even suggesting that the Joint Commission should be broken up, stimulating each of its members to pursue competing accreditation programs.<sup>196</sup> Though the antitrust law arguments in which Professor Havighurst finds legal support for his position are beyond the scope of this article,<sup>197</sup> the larger policy issues raised by him must be addressed.

There is much to be said for competing accreditation programs and for governmental recognition of multiple programs, where accreditation entities in fact articulate sufficiently distinct visions of health care to permit consumer

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193. Social Security Amendments of 1965, Pub. L. No. 89-97, sec. 102(a), § 1861(e)(6), 79 Stat. 286, 314-15, 326-27 (codified as amended at 42 U.S.C. § 1395bb (1988 & Supp. III 1991)).

194. See, e.g., *Thompson v. Sun City Community Hosp., Inc.*, 688 P.2d 605, 612 (Ariz. 1984) (holding that hospital may not transfer emergency room patient solely for financial reasons under Joint Commission standards incorporated by state law).

195. See Julie Johnsson, *Groups Vie for Lucrative Managed Care Accreditation Business*, HOSPITALS, Apr. 5, 1990, at 35, 38.

196. See Clark C. Havighurst & Nancy M. P. King, *Private Credentialing of Health Care Personnel: An Antitrust Perspective*, Part 2, 9 AM. J. L. & MED. 263, 323-25 (1983); Clark C. Havighurst, *Accreditation Competition Needed*, MOD. HEALTHCARE, Nov. 16, 1992, at 24.

197. See Clark C. Havighurst & Peter M. Brody, *Accrediting and the Sherman Act* 57 LAW & CONTEMP. PROBS. 199 (Autumn, 1994).

choice. Thus, the Medicare program has long recognized deemed status for both Joint Commission-accredited and American Osteopathic Association-accredited hospitals, permitting Medicare beneficiaries to make the relatively intelligible choice between osteopathic and allopathic hospitals.<sup>198</sup> The recent decision of HCFA to recognize both accreditation by the Community Health Accreditation Program and the Joint Commission for home health agencies arguably gives consumers a choice between home health programs that tend alternatively toward more of a nursing versus a medical orientation.<sup>199</sup> Where alternative accreditation programs do not offer consumers as apparent a philosophical choice, however, it is less clear that competing accreditation programs would be beneficial.

Examples of competition in health care that does not benefit consumers come readily to mind. Insurers have traditionally competed for identifying low-risk insureds (and eliminating high-risk insureds) rather than for offering the best benefit packages at the lowest cost.<sup>200</sup> Hospitals have traditionally competed to attract physicians who will increase admissions rather than to attract consumers by offering lower prices.<sup>201</sup> Given the difficulty patients have historically faced in obtaining and evaluating quality and price information regarding providers, it is not surprising that the health care industry has not performed like more traditional competitive markets where consumers can readily make informed choices.

Similarly, it is quite possible that multiple accreditors would compete in ways not beneficial to consumers. Since accreditors depend on fees paid by accredited institutions to survive, accreditors would be likely to compete first and foremost for the business of institutions seeking accreditation. In this market, those accreditors whose standards were most easily met or whose surveys were least intrusive would enjoy a competitive advantage. Alternatively, the accreditor with the lowest fees might gain an advantage, even if charging less meant less thorough accreditation surveys. Unless consumers had some means of evaluating the comparative quality of accreditation programs, it is unlikely that alternative accreditation entities would benefit consumers, or that multiple accreditors would compete to better serve them.

Were the government to recognize multiple accreditors, moreover, these accreditors may become more dependent upon the entities they accredit, and thus less free to exercise their independent professional judgment and less responsive as regulators. It was argued above that over the years the reliance of the federal and state governments on the Joint Commission for regulating

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198. 42 U.S.C. § 1395bb(a) (1988).

199. See Havighurst & King, *supra* note 196.

200. Stanley B. Jones, *Employer-Based Private Health Insurance Needs Structural Reform*, 29 INQUIRY 120, 121-23 (1992); Donald W. Light, *The Practice and Ethics of Risk-Rated Health Insurance*, 267 JAMA 2503 (1992).

201. Bruce C. Vladeck, *The Market vs. Regulation: The Case for Regulation*, 59 MILBANK MEM. FUND Q. 209, 216-17 (1981).

hospitals has both freed the Joint Commission to operate somewhat independently of the institutions it accredits and made it more responsive to government concerns (for example, disclosure of information and rigor of the accreditation process), because of its interest in maintaining government-endorsement of its programs. Were the Joint Commission merely one of several government-endorsed accreditors, this motivation might be severely diminished.

Where clear and easily understandable differences in accreditation philosophy exist, it makes sense to have multiple accreditors. Where differences among accreditors are less transparent to consumers, however, the public is better served by a single accreditor that is subject to rigorous governmental oversight, than by multiple accreditors competing for the favor of providers.

## VII

### CONCLUSION

Accreditation has traditionally been identified with industry self-regulation. The federal government's reliance on private accreditation for guaranteeing the quality of Medicare participating providers has thus been seen as suspect by those who fear that self-regulation is a poor vehicle for protecting consumers. The self-regulation model is too simplistic to explain the Joint Commission, however. The Joint Commission is responsive not only to the hospitals it accredits, but also to the physicians who created it and still play a major role in its governance, and to the federal and state governments whose recognition effectively gives the Joint Commission monopoly power in the hospital accreditation business. In the future, the Commission may also become responsive to the consumer or employer alliances that will direct the purchase of health care. Because it must respond to these various interests, the Joint Commission is arguably better able to assure the quality of health care than would be any simple self-regulatory body.

The Joint Commission could and should be more accountable to the public and more rigorous in the application of its accreditation standards. The federal government should be more rigorous in its validation process to assure the quality of Joint Commission decisions. The deemed status program, however, should be abandoned only if and when a more effective program can be devised to police and to encourage quality institutional health care. There is little reason to believe that such a program will be forthcoming.

